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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/512,124	08/26/2005	Genhong Cheng	02307K-154600US	8432

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EXAMINER	
DANG, IAN D	

ART UNIT	PAPER NUMBER
1647	

MAIL DATE	DELIVERY MODE
03/04/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/512,124	CHENG ET AL.	
	Examiner	Art Unit	
	IAN DANG	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5,20 and 25-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5,20 and 25-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 October 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments and/or Claims

The amendment of 21 November 2008 has been entered in full. Claims 1-4, 6-19, and 21-24 have been cancelled and claims 5 and 20 have been amended. Claims 27-31 have been added.

Claims 5, 20, 25-31 are under examination.

Sequence Compliance

The sequences appearing on pages 33, 34, and 47 of the specification have identified by SEQ ID NO in the amendments to the specification filed 08/26/2005. The sequences are now sequence compliant.

Claim Objections

The claim objections made to claims 5 and 20 have been withdrawn in view of the additions of the limitation reciting "an effective amount" in claims 5 and 20.

Rejections Withdrawn

35 USC § 112, Second paragraph

Applicant's response and amendments made to claims 5 and 20 filed on 11/21/2008 have overcome the rejection of claims 5 and 20 under 35 USC 112, Second paragraph. Applicant has provided the definition of the term "IRF3" and has deleted the term "TRL3/TRL4"

in claims 5 and 20. The rejection of claims 5 and 20 under 35 USC 112, Second paragraph has been withdrawn.

35 USC § 112, First paragraph (Written Description)

Applicant's response and amendments made to claims 5 and 20 filed on 11/21/2008 have overcome the rejection of claims 5 and 20 under 35 USC 112, First paragraph. Applicant has deleted the terms "IRF3 pathways", "TRL3/TRL4" and "imidazoquinolines compound" in claims 5 and 20. In addition, Applicant has added the limitation "increasing expression of interferon β in the cell" in claims 5 and 20. The rejection of claims 5 and 20 under 35 USC 112, First paragraph, has been withdrawn.

Rejection Maintained

Claim Rejections - 35 USC § 112, First paragraph (Enablement)

Claims 5, 20, 25, and 26 remain rejected under 35 U.S.C. 112, first paragraph, and the newly added claims 27, 29, and 31 are also rejected under 35 U.S.C. 112, first paragraph as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Although Applicants have partially overcome the enablement requirement by amending claims 5 and 20 with the removal of the limitation reciting "imidazoquinolines compound", the

rejection of claims 5, 20, 25, and 26 and for the newly added claims 27, 29, and 31 is maintained because Applicants are not enabled for any *in vivo* method for inhibiting a viral infection or replication.

As indicated in the previous Office action mailed 05/30/2008 (pages 7-9), the claimed invention is drawn to a method of inhibiting viral infection in a mammalian cell or in a human. Based on the disclosure of the specification, the Examiner has determined that Applicants is enabled for an *in vitro* method for inhibiting a viral infection or viral replication but not for an *in vivo* method.

At page 8 of the response, Applicants argue that the proposed meaning of the term "inhibiting" is clearly contrary to the repeated usage of the term in the specification and the reasonable interpretation to be made by those skilled in the art. However, this effect was inhibited by both IRF3-DBD and IKB-DA." (see, lines 8 and 9 at p. 39 of the specification). Looking at Fig. 3 C it is clear that the referenced inhibition was well short of being complete for either factor. In the more specific context of anti-viral effects, the specification sets forth that the "Activation of the TLR3/TLR4 signaling pathway was also found to potently inhibit viral infection by MHV68 through the autocrine/paracrine production of IFN β."(see, lines 8 and 9 on page 43). The use of the modifier potently would be superfluous if the specification used the term inhibiting to indicate a complete inhibition.

In addition, Applicants allege that the above-recited phrases of significantly inhibit, minor inhibition, and considerably weaker inhibition makes clear that the specification did not use the term "inhibit" to indicate a complete inhibition. Rather, given the repeated usages of "inhibition" in the specification, a person of skill in the art would readily understand that the "inhibition" represented by the claims need not be a complete or 100% inhibition.

Applicants' arguments have been considered but are found partially persuasive.

Based on the specification, the examiner agrees with Applicants that a person of skill in the art would readily understand that the "inhibition" represented by the claims need not be a complete or 100% inhibition.

In addition, although Applicants disclose an example illustrating that poly (I:C) can decrease viral replication in macrophages (Example 5, pages 60-61), the specification does not provide any guidance regarding the nexus between a decrease viral replication in macrophages induced by poly (I:C) and a method for inhibiting a viral infection in a mammalian cell or in a human by increasing the expression of interferon β in the cell or in a human. More specifically, the specification provides sufficient guidance for the inhibition of a viral infection of a cell *in vitro* but not *in vivo*. Since the the recitation of claims 5, 20, and 31 encompasses a method of inhibiting viral infection *in vivo*, these claims are not enabled based on the instant specification. In addition, the specification does not provide any guidance regarding how these examples would be indicative of a method for inhibiting a viral infection in a mammalian cell or a human by increasing the expression of interferon β in the cell or in a human. Since the Examiner has concerns about Applicants' examples being art accepted, the Examiner requests that Applicants support the assertion that their models were well known in the art to be indicative of a method for inhibiting a viral infection in a mammalian cell or a human by increasing the expression of interferon β in the cell or in a human. Without providing such disclosures, the claimed methods reciting in the claims of the instant application would require undue experimentation.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to IAN DANG whose telephone number is (571)272-5014. The examiner can normally be reached on Monday-Friday from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ian Dang
Patent Examiner
Art Unit 1647
February 19, 2009

/Robert Landsman/
Primary Examiner, Art Unit 1647